### <u>REMARKS</u>

The present application relates to hybrid maize plant and seed 35Y54. Claims 44, 47-48, and 53-54 have been canceled. Claims 8, 33-40, and 52 have been amended. Claim 55 has been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

### **Detailed Action**

# A. Status of the Application

Applicant acknowledges the indefiniteness rejection and the art rejection of record of all claims, except claim 8, have been overcome.

## B. Specification

Applicant submits the Deposit section on page 48 has been amended in order to properly include both the hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 within the Deposit paragraph. The changes do not add new matter as there is literal support for the minor changes on pages 7 in the originally filed specification. The specification has now been amended to correct these minor changes.

In addition, Applicant respectfully submits that the actual ATCC deposit of the two inbred plants will be delayed until the receipt of notice that the application is otherwise in condition for allowance, in compliance under 37 C.F.R. §§ 1.801-1.809. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination and the name and address of the depository. The claims will also be amended to recite the ATCC deposit number. Applicant submits that at least 2,500 seeds of hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 will be deposited with the ATCC. Applicant further asserts that the deposits will be made without restriction.

# Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 8 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant

regards as the invention, for the reasons of record stated in the Office Action mailed December 11, 2002.

Applicant traverses this rejection. Applicant has now amended claim 8 to delete the terminology "has been manipulated to be male sterile" and include the recitation --an introgressed cytoplasmic gene that confers male sterility--, thus alleviating this rejection.

Claims 34-35 and 38-40 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 34-35 and 38-40 stand rejected for the recitation "maize plant" as confusing the dependence upon claims 33 and 37, respectively, which are drawn to a method.

Applicant has amended claims 34-35 and 38-40 to include the terminology --maize plant produced by the method--, as suggested by the Examiner, thereby obviating this rejection.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

## Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 37-40, 47, 48, and 54 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that there is no literal basis in the specification for the terms: "backcross conversion 35Y54 hybrid maize plant", "double haploid method", "75% genetic identity", and "pedigree...has 2 or less breeding crosses".

Applicant respectfully traverses this rejection. However, in an effort to expedite prosecution, Applicant has canceled claims 47, 48, and 54, thus alleviating this rejection. Claims 37-40 have been amended. Applicant has amended claim 37 to include --wherein said backcross conversion mutant gene or transgene is selected from the group consisting of a plant disease resistance gene, an insect resistance gene, an herbicide resistance gene, and a male sterility gene, and a gene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism--, thereby limiting the claims to the types of transgenes that may be introduced and that are supported by the specification on pages 40-46.

Applicant has amended the claims to be in the format indicated as allowable by the claims faxed by SPE Amy Nelson and Examiner David Fox. Further, claim 55 is a method claim that is adequately described in the specification on page 5, first full paragraph, thereby alleviating this rejection. Applicant asserts, as stated in the written description guidelines, an old process performed with a novel material is novel in and of itself. 66 Federal Register 1099, Vol. 66, No. 4 (January 5, 2001). See Example 10, Revised Interim Written Description Guidelines Training Materials, in which claim 1 therein is indicated as allowable. Applicant respectfully submits the claims now come within the purview of the written description requirement and request reconsideration.

Claims 33-40, 45, and 48 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is more nearly connected, to make and/or use the invention. The Examiner states since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 within the Deposit paragraph on page 48. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The specification has now been amended to correct these minor changes. Applicant thanks the Examiner for pointing out this inadvertent mistake.

In addition Applicant submits that the actual ATCC deposit will be delayed until receipt of notice that the application is otherwise in condition for allowance. As provided in 37 C.F.R. §§ 1.801-1.809, Applicant wishes to reiterate they will refrain from deposit of hybrid 35Y54 and inbred parents GE570932 and GE486862 until allowable subject matter is indicated. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, description of the deposited biological materials sufficient to specifically identify and to permit examination and the name and address of the depository. The claims will also be amended to recite the proper ATCC deposit numbers. The Applicant provides assurance that:

- a) during the pendency of this application access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of thirty years, or five years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit will be conducted (see 37 C.F.R. § 1.807); and
- e) the deposit will be replaced if it should ever become inviable. Therefore, Applicant submit at least 2500 seeds of hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 will be deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02) Such action is respectfully requested.

Claims 8, 33-35, 37-40, 44, and 47-54 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office Action for claims 8-19 and 21-32. The Examiner stated that claims 12, 15, 25, 28 and dependents thereon are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plant. The Examiner further stated that claims 8, 16, 19, 21, 29, 32 and dependents thereon are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants.

Applicant respectfully traverses this rejection. Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. As stated in

Poehlman *et al.* (1995) on page 334, submitted in the Information Disclosure Statement, "a backcross derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Applicant further points out that cytoplasmic male sterility genes do not introduce linked nuclear genes. Wych (1988) on page 585-586, submitted in the Information Disclosure Statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile inbred to be the same variety as the F1 hybrid produced with the fertile version of the inbred. Applicant also refers the Examiner to Openshaw *et al.* submitted herewith as Appendix A, which states the "the backcross breeding procedure is being used widely to transfer simply inherited traits into elite genotypes...Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm."

Nonetheless, in an effort to expedite prosecution, Applicant has canceled claims 44, 47-48, and 53-54 have been canceled. Claims 8, 33-40, and 52 have been amended. Claim 37 has been amended to include --wherein said backcross conversion mutant gene or transgene is selected from the group consisting of a plant disease resistance gene, an insect resistance gene, an herbicide resistance gene, and a male sterility gene, and a gene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism--, thereby limiting the claims to the types of transgenes that may be introduced and that are supported by the specification as aforementioned. Applicant respectfully submits the claims come within the purview of the written description requirement and request reconsideration.

Claims 8, 33-35, 37-40, 44, and 47-54 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons stated in the last Office Action for 8, 12-19, 21 and 25-32.

Applicant respectfully traverses this rejection. In an effort to expedite prosecution, Applicant has canceled claims 44, 47-48, and 53-54. Claims 8, 33-40, and 52 have been

amended. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 within the Deposit paragraph on page 48. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The Specification has now been amended to correct these minor changes. The Applicant further provides assurance that at least 2500 seeds of hybrid maize plant 35Y54 and the inbred parents GE570932 and GE486862 have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02).

In addition, the Applicant would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

Further, Applicant asserts transformation and backcrossing are two techniques that may be utilized to add a desirable trait to an already developed inbred or hybrid. As described herein and in the specification, such techniques are well known to those of ordinary skill in the art and may be practiced on the deposited material. Applicant has also added claim 55 to further describe the line produced in such a manner by traits that do not vary from the deposited line at a 5% significance level when measured in the same environmental conditions. Phenotypic traits, an identifying characteristic, are a method utilized by those of ordinary skill in the art to compare two lines, and are the method used by the patent office to evaluate the novelty of the deposited line itself. One of ordinary skill in the art of plant breeding would know how to evaluate the traits of two plant varieties to determine if there is no statistically significant variation when determined, for example, at a 5% significance level and when grown in the same environmental conditions between the traits expressed by those varieties. For the reasons aforementioned, it is respectfully submitted that Applicants' claims are sufficiently described and enabled by the specification.

In light of the above amendments and remarks, Applicant respectfully request reconsideration and withdrawal of the rejections to claims 8, 33-35, 37-40, 44, and 47-54 under 35 U.S.C. § 112, first paragraph.

### **Summary**

Applicant acknowledges that claims 1-7, 20, 41-43, and 46 are allowed.

Applicant further acknowledges that claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 are deemed free of the prior art. The Examiner further states the prior art fails to teach or fairly suggest the particularly claimed maize plants with their unique complement of genotypic and morphological characteristics, or methods of using them. This clearly indicates that hybrid maize plant 35Y54 as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness. Therefore, Applicant respectfully submits that the deposit of the representative seed of 35Y54 and inbred parents GE570932 and GE486862 should satisfy the description requirement. In light of the above, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph as improper and requests reconsideration and withdrawal of these rejections.

#### Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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